K122688

510(k) Summary

APR 4 2013

A. Date Prepared:

November 8, 2012

B. 510(K) Owner:

Nova Biomedical Corporation
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Waltham, MA 02454 USA
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Registration Number: 1219029

C. Device Information

Proprietary Name:

Nova Max Mini Blood Glucose and β-Ketone Monitor System

Common Or Usual Name:

Blood Glucose and β-Ketone Monitor

Classification Name:

System, Test, Blood Glucose, Over the Counter

4. Classification:

Class II (assay) and Class I, Reserved Controls

5. Product Codes:

NBW, Blood Glucose Test System, Over-the-Counter
LFR, Glucose Dehydrogenase
JJY, Multi-Analyte Controls
JIN, Ketones

6. Regulatory Section:

21 CFR 862.1345, Glucose Test System
21 CFR 862.1660, Quality Control (assayed and unassayed)
21 CFR 862.1435, Ketone Test System

7. Panel:

Clinical Chemistry (75)

D. Intended Use:

The Nova Max Mini Blood Glucose and β-Ketone Monitor System is intended to be used for the quantitative measurement of glucose or β-hydroxybutyrate (β-ketone) in fresh capillary whole blood. It is intended for single-patient home use and should not be used for testing multiple patients. It is intended for self-testing outside the body by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control. The Nova Max Mini Blood Glucose and β-Ketone Monitor System is specifically indicated for the quantitative measurement of glucose in fresh capillary whole blood obtained from the fingertip or alternative site testing on the forearm, or β-ketone in whole blood capillary samples

obtained from the fingertip only. Glucose AST on the forearm can be used only during steady-state blood glucose conditions.

The Nova Max Mini is not intended for the diagnosis of or screening for diabetes, and it is not intended for use on neonates.

The Nova Max Mini Blood Glucose Test Strips are intended for use only with the Nova Max Mini Blood Glucose Monitor System to quantitatively measure capillary blood glucose from the finger and forearm.

The Nova Max Mini Ketone Test Strips are intended for use only on the Nova Max Mini Blood Glucose and β-Ketone Monitor System to quantitatively measure capillary β-hydroxybutyrate from the finger.

Nova Max Mini Glucose/Ketone Control Solutions are intended for use with the Nova Max Mini Glucose and β-Ketone Monitor and test strips as a quality control check to verify the accuracy of test results. There are two levels of controls, (Level 2 and Level 3).

E. Device Description:

Nova Max Mini Blood Glucose and β-Ketone Monitor

The monitor is a hand-held testing device that works in conjunction with Nova Max Mini glucose test strips to measure glucose or the Nova Max Mini β-Ketone test strips to measure β-ketone in a whole blood sample. Monitor operation is self-prompting using three user interface buttons. In addition to measuring glucose and ketone, the monitor also stores patient test and quality control test data.

The self-prompting menu system is navigated by means of a three-button keypad. It offers audible feedback for user inputs, and audible and/or visual feedback for prompts and user alerts.

A "battery low" warning will alert the user to change the batteries. Battery charge state information is available on the "monitor status screen". The user can select the auto shutoff option to conserve power when the monitor is not in use. Test data and monitor setup information will be stored in a non-volatile format to prevent data loss.

Nova Max Mini Blood Glucose Test Strips

The test strips contain a reaction layer that contains a glucose-enzyme (greater than 1.0 IU) and ferricyanide as a mediator and will utilize glucose dehydrogenase flavin-adenine dinucleotide (GDH-FAD) chemistry (*Aspergillis sp.*). The test strip is touched to a drop of blood to initiate the test process. The strip is designed such that when a drop of blood is touched to the end of the strip, the blood is drawn into the reaction space via capillary action. A simple one-step process provides a blood glucose result. Ten test strips will be provided with the meter kit and will also be available separately in vials of 50 strips. These test strips are manufactured by Nova Biomedical and identical to those cleared for market with the predicate Nova Max One Blood Glucose Monitor System (K112638).

Nova Max Mini β-Ketone Test Strips

The Nova Max Mini β-Ketone test strips contain a reaction layer that contains the enzyme β-hydroxybutyrate dehydrogenase (*Alcaligenes fecalis*) greater than or equal to 0.3 IU; mediator greater than or equal to 0.42 µg: coenzyme equal or greater than 0.28 µg and additional ingredients (polymers, buffers). The test strip is touched to a drop of blood to initiate the test process. The strip is designed such that when a drop of blood is touched to the end of the strip, the blood is drawn into the reaction space via capillary action. This simple one-step process provides a blood β-Ketone result displayed on the monitor. Two ketone test strips will be provided with the meter kit and will also be available separately in cartons of 10 strips. Ketone strips are individually packaged in foil pouches. The ketone test strip is identical to the strip cleared for market with the predicate Nova Max Plus Blood Glucose and β-Ketone Monitor (K091547).

Control Solutions

The control solutions are aqueous assayed solutions, containing buffered D-Glucose, β-Ketone, viscosity-adjusting agent, preservatives and other non-reactive ingredients (dye). They contain no products of human origin. There are two levels of controls, (Level 2 and Level 3). One level of control (Level 2) will be provided with the monitor and both levels will be available for sale separately from the monitor. These controls are manufactured by Nova Biomedical and identical to those cleared for market as Nova Max Plus Glucose and β-Ketone Control Solution (K101633).

F. Summary of Technological Characteristics:

The Nova Max Mini Blood Glucose and β-Ketone Monitor is the same device cleared in K091547 (Nova Max Plus Blood Glucose and β-Ketone Monitor System) and K112638 (Nova Max One Blood Glucose Monitor) and has the same fundamental scientific technology. The Nova Max Mini Blood Glucose and β-Ketone Monitor is substantially equivalent to the Nova Max Plus Blood Glucose and β-Ketone Monitor and the Nova Max One Blood Glucose Monitor.

The Nova Max Mini Blood Glucose Monitor measures glucose electrochemically as described in K112638 (Nova Max One Glucose Monitor System) and measures ketone electrochemically as described in K091547 (Nova Max Plus Blood Glucose and β-Ketone Monitor). In the same manner, the magnitude of the current is proportional to the amount of glucose or ketone present in the sample, providing a quantitative measure of glucose or ketone in whole blood and control solutions.

G. Predicate Device:

K091547 – Nova Max Plus Blood Glucose and β-Ketone Monitor System

K112638 - Nova Max One Blood Glucose Monitor System

H. Comparison to Predicate Devices:

The Nova Max Mini Blood Glucose and β-Ketone Monitor, while smaller than both the Nova Max Plus (K091547) and the Nova Max One (K112638) Monitors, has the same fundamental scientific technology and user interface. The only changes made to the components of the system as compared to the cleared systems (K091547 and K112638) are the smaller housing and display. The Nova Max Mini Monitor has the same indications for use as the Nova Max Plus Monitor System and uses the same technology for glucose measurement as the Nova Max One Monitor System. The Nova Max Mini Blood Glucose and β-Ketone Monitor is substantially equivalent to the Nova Max Plus Blood Glucose β-Ketone and Nova Max One Glucose Monitor System. Please see the table *Comparison of Predicate and Proposed Devices* below.

I. Performance Studies:

The performance of the Nova Max Mini Blood Glucose and β-Ketone Monitor was studied in the laboratory settings. The studies demonstrated that the device can provide glucose or ketone results that are substantially equivalent to the current methods for blood glucose and ketone measurements obtained from capillary blood.

J. Conclusion:

Results of laboratory testing demonstrate that the Nova Max Mini Blood Glucose and β-Ketone Monitor produces results that are substantially equivalent to results obtained on the predicate devices. The system performs as intended and raises no new safety or effectiveness issues.

Comparison of Predicate and Proposed device

Characteristic	**Predicate** - Nova Max One Blood Glucose Monitor System - K112638	**Predicate** – Nova Max Plus Blood Glucose and β-Ketone Monitor System – K091547	**Proposed** - Nova Max Mini Blood Glucose and β-Ketone Monitor System
Test Measured	Glucose	Glucose or β-Ketone	Glucose or β-Ketone
Operating Principle	Coulometric Electro-chemical Sensor	Coulometric Electro-chemical Sensor	Coulometric Electro-chemical Sensor
Intended Use	The Nova Max One Blood Glucose Monitor is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. It is intended for single-patient home use and should not be used for testing multiple patients. It is intended for self testing outside the body by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control. The Nova Max One Blood Glucose Monitor is specifically indicated for the quantitative measurement of glucose in fresh whole blood capillary samples obtained from the fingertip or alternative site testing (AST) on the forearm. AST on the forearm can be used only during steady-state blood glucose conditions. It is not intended for the diagnosis of or screening for diabetes, and it is not intended for use on newborns.	The Nova Max Plus Glucose and β-Ketone Monitoring System is intended to be used for the quantitative measurement of glucose or β-hydroxybutyrate (β-Ketone) in fresh capillary whole blood. It is intended for use by people with diabetes mellitus in the home and by healthcare professionals in clinical settings as an aid to monitor the effectiveness of diabetes control. It is not intended for use in the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates. The Nova Max Plus Monitor is specifically indicated for the quantitative measurement of glucose in fresh capillary whole blood samples obtained from the fingertip, forearm, and palm or β-ketone in fresh capillary whole blood samples obtained from the fingertip only.	The Nova Max Mini Blood Glucose and β-Ketone Monitor System is intended to be used for the quantitative measurement of glucose or β-hydroxybutyrate (β-ketone) in fresh capillary whole blood. It is intended for single-patient home use and should not be used for testing multiple patients. It is intended for self-testing outside the body by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control. The Nova Max Mini Blood Glucose and β-Ketone Monitor System is specifically indicated for the quantitative measurement of glucose in fresh capillary whole blood obtained from the fingertip or alternative site testing on the forearm, or β-ketone in whole blood capillary samples obtained from the fingertip only. Glucose AST on the forearm can be used only during steady-state blood glucose conditions. The Nova Max Mini is not intended for the diagnosis of or screening for diabetes, and it is not intended for use on neonates.

Characteristic	**Predicate** - Nova Max One Blood Glucose Monitor System - K112638	**Predicate** – Nova Max Plus Blood Glucose and β-Ketone Monitor System – K091547	**Proposed** - Nova Max Mini Blood Glucose and β-Ketone Monitor System
			The Nova Max Mini Blood Glucose Test Strips are intended for use only with the Nova Max Mini Blood Glucose Monitor System to quantitatively measure capillary blood glucose from the finger and forearm. The Nova Max Mini Ketone Test Strips are intended for use only on the Nova Max Mini Blood Glucose and β-Ketone Monitor System to quantitatively measure capillary β-hydroxybutyrate from the finger. Nova Max Mini Glucose/Ketone Control Solutions are intended for use with the Nova Max Mini Glucose and β-Ketone Monitor and test strips as a quality control check to verify the accuracy of test results. There are two levels of controls, (Level 2 and Level 3).
GLU Measuring Range	20-600 mg/dL	20-600 mg/dL	20-600 mg/dL
KET Measuring Range	N/A	0.1 – 8.0 mmol/L	0.1 – 8.0 mmol/L
Hematocrit Range	25% to 60%	25% to 60%	25% to 60%
Sample type	Capillary blood from the fingertip, forearm	Capillary blood from the fingertip, forearm and palm (Ketone fingertip only)	Capillary blood from the fingertip, forearm (Ketone fingertip only)
GLU Sample size	0.4 µL	0.3 µL	0.4 µL

Characteristic	**Predicate** - Nova Max One Blood Glucose Monitor System - K112638	**Predicate** – Nova Max Plus Blood Glucose and β-Ketone Monitor System – K091547	**Proposed** - Nova Max Mini Blood Glucose and β-Ketone Monitor System
Glucose Units	mg/dL	mg/dL	mg/dL
Ketone Units	N/A	mmol/L	mmol/L
Sample application	Test strip capillary draw	Test strip capillary draw	Test strip capillary draw
Handheld meter	Yes	Yes	Yes
Data storage	Up to 400 blood glucose and control solution tests	Up to 400 blood glucose and control solution tests	Up to 400 blood glucose and control solution tests
GLU Analysis Time	4 seconds	5 seconds	4 seconds
Insulin Tracking	No.	No	No.
KET Analysis Time	N/A	10 seconds	10 seconds
Power source	3 volt coin cell battery	3 volt coin cell battery	3 volt coin cell battery
GLU Test Strips Active reagent:	Glucose Dehydrogenase - FAD	Glucose Oxidase	Glucose Dehydrogenase - FAD
KET Test Strips Active reagent	N/A	β-hydroxybutyrate dehydrogenase	β-hydroxybutyrate dehydrogenase
Test Strip Calibration Coding	No User Input of Calibration code required	No User Input of Calibration code required	No User Input of Calibration code required
Lancing Device:	Nova Reusable Lancing Device and Lancets	Nova Reusable Lancing Device and Lancets	Nova Reusable Lancing Device and Lancets

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 4, 2013

Nova Biomedical Corporation
c/o Paul MacDonald, Ph.D.
200 Prospect Street
WALTHAM MA 02454

Re: k122688
Trade/Device Name: Nova Max Mini Blood Glucose and ß-ketone Monitor System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR, JJY, JIN
Dated: March 22, 2013
Received: March 25, 2013

Dear Dr. MacDonald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K122688

Device Name: Nova Max Mini Blood Glucose and β-Ketone Monitor System

Indications for Use:

The Nova Max Mini Blood Glucose and β-Ketone Monitor System is intended to be used for the quantitative measurement of glucose or β-hydroxybutyrate (β-ketone) in fresh capillary whole blood. It is intended for single-patient home use and should not be used for testing multiple patients. It is intended for self-testing outside the body by people with diabetes mellitus as an aid to monitor the effectiveness of diabetes control. The Nova Max Mini Blood Glucose and β-Ketone Monitor System is specifically indicated for the quantitative measurement of glucose in fresh capillary whole blood obtained from the fingertip or alternative site testing on the forearm, or β-ketone in whole blood capillary samples obtained from the fingertip only. Glucose AST on the forearm can be used only during steady-state blood glucose conditions.

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The Nova Max Mini Ketone Test Strips are intended for use only on the Nova Max Mini Blood Glucose and β-Ketone Monitor System to quantitatively measure capillary β-hydroxybutyrate from the finger.

Nova Max Mini Glucose/Ketone Control Solutions are intended for use with the Max Mini Glucose or β-Ketone Test Strips as a quality control check to verify the accuracy of test results. There are two levels of controls, (Level 2 and Level 3).

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __X_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)

Katherine Serrano

Division Sign-Off
Office of In Vitro Devices and Radiologic Health

510(k) k122688